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TYPE OF PAPER TRANSMITTED: LETTER TO EXAMINER

APPLICANT'S NAME: J. Alexander Marchosky

SERIAL NO.: 10/071,490

EXAMINER: Blessing Fubara

APPLICATION TITLE: COMPOSITIONS AND METHODS FOR FORMING AND STRENGTHENING BONE

Original will/will not be mailed
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August 16, 2005

Examiner Blessing Fubara
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Divisional Patent Application No. 10/071,490 entitled COMPOSITIONS
AND METHODS FOR FORMING AND STRENGTHENING BONE
Our File: 60019660-0021

Dear Examiner Fubara:

Thank you for your discussion yesterday. As we discussed preliminarily, we would suggest going with pending claims 95 - 103 inserting "one or more of" into claim 95, and related changes, as you had proposed in your unofficial draft to me. (See attached.) We would then also suggest a similar claim set based on 95 - 103, deleting the "compound selected from" verbiage, to read simply:

"A composition for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid, cancellous bone, and demineralized bone matrix."

The "one or more" is expressly supported in the application at pages 4 - 6.

The remaining claims would be canceled.

Please let me know if you believe this is an appropriate basis for an Examiner's amendment.

Best regards,


Harley Blosser

To :

Harley Blosser

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Per our conversation
follows → the amended are not included in the
copy. P/s Any should! be
change to the
→ Please comment.

Erin Blosser

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DETAILED ACTION

Examiner acknowledges receipt of non-complaint amendment and compliant amendment to the claims filed 02/01/05 and 02/28/05 respectively, amendment to the specification filed 02/01/05, and remarks filed 02/01/05 and 02/28/05. Claims 1-103 are pending.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with G. Harley Blosser on 05/17/05.

The application has been amended as follows: In the claims, replace original claim 56, previously presented claims 68, 69, 71 and 75, previously amended claim 72 and new claims 77, 83, 87, 88, 90, 91, 94-97 and 99-103 with Examiners amended claims 56, 68, 69, 71, 72, 75, 77, 83, 87, 88, 90, 91, 94-97 and 99-103 below.

56. A composition for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid, cancellous bone, and demineralized bone matrix; and optionally a compound selected from the group consisting of vascular endothelial growth factor, bone morphogenic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, platelet derived growth factors, transforming growth factors, placental growth factors

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granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins and non-decalcified bone matrix.

68. A composition as set forth in claim 56 wherein the compound selected from the group consisting of vascular endothelial growth factor, bone morphogenic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, platelet derived growth factors, transforming growth factors, placental growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics and vitamins is present.

69 A composition as set forth in claim 68 wherein the compound is vascular endothelial growth factor.

71. A composition as set forth in claim 65 where the non-decalcified bone matrix is present at 5-30%.

72. A method of inducing bone formation in a vertebrate comprising applying an effective amount of a composition consisting essentially of a mixture of hyaluronic acid, cancellous bone, and demineralized bone matrix; and optionally a compound selected from the group consisting of vascular endothelial growth factor, bone morphogenic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, platelet derived growth factors, transforming growth factors, placental growth factors granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins and non-decalcified bone matrix.

75. A method of filling a bone defect comprising filling the bone defect site with a composition consisting essentially of a mixture of hyaluronic acid, cancellous bone, and demineralized bone matrix; and optionally a compound selected from the group consisting of vascular endothelial growth factor, bone morphogenic proteins, fibroblast growth factors, tumor necrosis factor,

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endothelial cell growth factors, platelet derived growth factors, transforming growth factors, placental growth factors granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins and non-decalcified bone matrix.

77. A method of filling a bone defect as set forth in claim 75 wherein ~~any~~ ^{the} bone material consists essentially of bone allograft material.

83. A composition consisting essentially of a mixture of hyaluronic acid, cancellous bone, and demineralized bone matrix; and optionally a compound selected from the group consisting of vascular endothelial growth factor, bone morphogenic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, platelet derived growth factors, transforming growth factors; placental growth factors granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins and non-decalcified bone matrix; wherein ~~any~~ ^{the} bone material consists essentially of bone allograft material.

87. A composition as set forth in claim 83 wherein the compound selected from the group consisting of vascular endothelial growth factor, bone morphogenic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, platelet derived growth factors, transforming growth factors, placental growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics and vitamins is present.

88. A composition as set forth in claim 87 further wherein the compound is a vascular endothelial growth factor.

90. A composition as set forth in claim 84 where the non-decalcified bone matrix is present at 5-30%.

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91. A composition for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid, cancellous bone, and demineralized bone matrix; and optionally a compound selected from the group consisting of vascular endothelial growth factor, bone morphogenic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, platelet derived growth factors, transforming growth factors, placental growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins and non-decalcified bone matrix.

94. A composition as set forth in claim 91 wherein the hyaluronic acid is present at 10-80% (w/w), the cancellous bone is present at 10-40% (w/w), and the demineralized bone matrix is present at 5-30%.

95. A composition for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid, cancellous bone, demineralized bone matrix, and one or more of a compound selected from the group consisting of vascular endothelial growth factor, bone morphogenic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics and vitamins.

96. A composition as set forth in claim 95 wherein one or more of the compound is a vascular endothelial growth factor.

97. A composition as set forth in claim 95 wherein ^{the} any bone material consists essentially of bone allograft material.

98. The method of claim 98 wherein the cancellous bone is present at 10-50% (w/w).

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100. The method of claim 98 wherein the cancellous bone is milled to 0.1-1.5 mm in its longest diameter.

101. The method of claim 98 wherein the hyaluronic acid is present at 10-80% (w/w), the cancellous bone is present at 10-40% (w/w), and the demineralized bone matrix is present at 5-30%.

102. A method of inducing bone formation in a vertebrate comprising applying a composition for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid, cancellous bone, demineralized bone matrix, and one or more compounds selected from the group consisting of vascular endothelial growth factor, bone morphogenic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics and vitamins.

103. The method of claim 98 wherein ^{the}any bone material consists essentially of bone allograft material.

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